

## **REMARKS**

### **Status of the Claims**

Claims 12-15 and 18-26 are pending in the present application. Claims 1-11, 17, and 27 were previously canceled. Claim 16 is presently canceled. Claim 12 is amended. Support for the amendment to claim 12 is found throughout the application as originally filed including on page 6, original claim 16, and page 7. No new matter is entered by way of this amendment. Reconsideration is respectfully requested.

### **Examiner Interview**

Applicants and Applicants' representative would like to thank the Examiner for extending the courtesy of an interview on February 4, 2011. The substance of the interview is essentially as described in the Examiner interview summary, which issued on February 10, 2011.

### **Issues under 35 U.S.C. § 112, Second Paragraph**

Claims 12-16, 18, 19, 25, and 26 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite, *see* Office Action, pages 2-3.

According to the Examiner, the phrase "fat cells" in claim 12 is unclear. The Examiner states that the specification discloses that cells isolated from fat tissue include fat cells, fat precursor cells, and somatic stem cells, which are Lin-negative, c-Kit-negative to weak-positive, and  $\beta 1$  integrin-positive cells. The Examiner also asserts that the inventor's own publication (Yamada *et al.*, *Biochemical and Biophysical Research Communications*, 2006, 342:662-670) discloses that  $\beta 1$  integrin or CD29 is a marker for stem/progenitor cells in brown adipose tissue (BAT) derived cells (BATDCs). The Examiner additionally points out that it appears that fat cells, fat precursor cells, and somatic stem cells, which are confirmed to be CD29 positive, are either stem or progenitor cells present in fat tissue, and this is contradicting disclosure when "fat cells" are considered to be differentiated adipocytes.

Applicants submit that the "fat cells" described in previously pending claim 1 are described in the originally filed application as "multipotent cells" on page 2, lines 15-20:

*Fat tissues are easily obtainable. Multipotent cells have been isolated from human fat tissues, and differentiation thereof into nerve cells was recently observed (Zuk P. A. et al., "Multilineage Cells from Human Adipose Tissue: Implications for Cell-Based Therapies," Tissue Engineering, Vol. 7, No. 2, 2001, pp. 211-228; Zuk P. A.*

*et al.*, "Human Adipose Tissue Is a Source of Multipotent Stem Cells," *Molecular Biology of the Cell*, Vol. 13, pp. 4279-4295, 2002).

Applicants further submit that CD29 ( $\beta$ 1 integrin) is expressed in mesenchymal stem cell enriched populations as mentioned in Yamada *et al.*, *Biochemical and Biophysical Research Communications*, 2006, 342:662-670, and other prior-art documents. CD29 ( $\beta$ 1 integrin) is also expressed in a variety of blood cells and normal mesenchymal cells. Accordingly, cells expressing Lin-negative, c-Kit-negative to weak-positive, and  $\beta$ 1 integrin (CD29)-positive cell markers are not considered to be differentiated blood cells. These cells contain multipotent cells and/or a fraction of mesenchymal stem cells. Further, such cells are considered to be similar to mesenchymal stem cells due to the c-Kit weak-positive expression.

In view of the foregoing, and in an effort to expedite prosecution, claim 12 is amended according to the Examiner's suggestions in the February 4, 2011, interview to specify "culturing said bone marrow cells or cord blood-derived cells with Lin-negative, c-Kit-negative, and  $\beta$ 1 integrin-positive cells isolated from mammalian fat tissues" rather than "fat cells, fat precursor cells and somatic stem cells isolated from mammalian fat tissues." Accordingly, Applicants believe this rejection is overcome and respectfully request withdrawal.

#### **Issues under 35 U.S.C. § 112, First Paragraph**

##### *Bone Marrow*

Claims 12-15, 18, 19, 25, and 26 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking enablement, *see Office Action*, page 3. The Examiner indicates that the present claims describe culturing bone marrow cells with fat cells, fat precursor cells, and somatic stem cells isolated from mammalian fat tissues, wherein the bone marrow cells are induced to differentiate into myocardial precursor cells and/or myocardial cells. The Examiner states that it is well known that terminally differentiated cells or those which have lost the ability to differentiate into myocardial lineage are not capable of differentiating into myocardial cells. Accordingly, the Examiner believes that the term "bone marrow" is too broad since it encompasses, for example, terminally differentiated cells. The Examiner recommends that Applicants amend claim 12 to incorporate the subject matter of claim 16 to limit the bone marrow cells to either mesenchymal or hematopoietic stem cells.

Although Applicants do not agree with the Examiner's assertions, claim 12 is amended as the Examiner suggests. Accordingly, Applicants believe this aspect of the rejection is overcome and respectfully request withdrawal.

*Cord Blood*

The Examiner further rejects claims 12-15, 18, 19, 25, and 26 as allegedly lacking enablement due to the recitation of "cord blood", *see Office Action*, page 4. According to the Examiner, not all mononuclear cells from cord blood are capable of differentiating into myocardial cells. The Examiner indicates that the mononuclear cell fractions obtained from cord blood, as described in the examples of the present application, must contain stem and/or progenitor cells. Accordingly, the Examiner advises Applicants to amend the claims to limit the cord blood cells to stem and/or progenitor cells, without introducing any new matter into the claims.

During the February 4, 2011, interview, the Examiner suggested that claim 12 be amended to specify "wherein the cord blood-derived cells are mononuclear cells, that can be induced to differentiate into myocardial precursor cells and/or myocardial cells." Although Applicants do not agree with the Examiner, the claims are amended according to the Examiner's suggestions in an effort to expedite prosecution. As noted above, support for this amendment is found, for example, on page 7 in the originally filed application.

In view of the foregoing, Applicants believe that this aspect of the rejection is overcome. Accordingly, withdrawal of the rejection is respectfully requested.

**CONCLUSION**

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Linda T. Parker, Ph.D., Registration No. 46,046, at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

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Respectfully submitted,

By 

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